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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,025	11/13/2001	Albert Boronat	MONS:039USC1	6556
32425	7590	10/22/2003	EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/987,025

Applicant(s)

BORONAT ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-34 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 21-34 and 36-39 are pending. Claims 1-20 and 35 are cancelled.

Claims 21-34 and 36-39 are examined.

Rejection of Claims 22-35 under 35 U.S.C. 102(b) as being anticipated by Burkhardt P. *et al.* (The Plant Journal, 1997; Vol. 11, No. 5; pp. 1071-1078) is withdrawn in view of Applicant's amendments.

Rejection of Claims 21-24 and 36-39 under 35 U.S.C. 102(a) as being anticipated by Sato S. *et al.* is withdrawn in view of Applicant's amendments and arguments.

Rejection of Claims 21-34 and 36-39 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments and arguments.

### ***Claim Rejections - 35 USC § 112***

Claims 21-34 and 36-39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/12/2003. Applicant's arguments filed 7/15/2003 have been considered but are not deemed persuasive.

Applicant asserts that the phrase "stringent hybridization conditions" recited in the claims and described in the specification is sufficient to overcome the written description rejection (response page 11). The definition for 'stringent conditions', does not exclude unrecited hybridization conditions. Limitations recited in the specification are not to be read into the claims. Hybridization and wash conditions are to be recited in the claim itself.

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Applicant asserts that the specification describes the rejected claims that are drawn to isolated polynucleotides having at least 70% to 95% sequence identity to SEQ ID NO: 1 (response page 11). The specification does not provide support for a written description of an isolated polynucleotide sequence having 70%, 80% or 90% sequence identity to SEQ ID NO: 1 and encoding a 1-deoxy-D-xylulose 5-phosphate reductoisomerase either by a recitation of the hybridization and wash conditions of high stringency in the claim or by a description in the specification of conserved structural features that could be correlated with function of a polynucleotide sequence having 70%, 80% or 90% sequence identity to SEQ ID NO: 1 and also encode a 1-deoxy-D-xylulose 5-phosphate reductoisomerase.

Claims 21-34 and 36-39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/12/2003. Applicant's arguments filed 7/15/2003 have been considered but are not deemed persuasive.

Applicant asserts that they teach methods for modifying or altering the isoprenoid content of host cells and plants and recites where they are taught in the specification (response page 13). Applicant does not teach a method of analyzing a plant for altered isoprenoid content or a phenotype of a plant transformed with a 1-deoxy-D-xylulose 5-phosphate reductoisomerase and having an altered isoprenoid content.

Applicant asserts that the specification teaches methods of isolation of 1-deoxy-D-xylulose 5-phosphate reductoisomerase encoding polynucleotides by recitation of stringent conditions in the specification (response page 13). Applicant has recited hybridization and wash conditions for isolating polynucleotides that have at least 95% sequence identity to SEQ ID NO: 1 but has not provided guidance for isolating polynucleotides encoding a 1-deoxy-D-xylulose 5-phosphate reductoisomerase that may not bear so close a resemblance to SEQ ID NO: 1, namely those having 70%, 80% or 90% sequence identity to SEQ ID NO: 1 by a recitation of the hybridization and wash conditions of high stringency in the claim and by a description of conserved structural features of a 1-deoxy-D-xylulose 5-phosphate reductoisomerase that could be correlated with function and thus Applicant has not taught how to predictably eliminate sequences that do not embody the invention. Further, as discussed above, the definition for 'stringent conditions' in the specification, and recitation of a single example of such conditions does not exclude other hybridization conditions.

Applicants argue that they have taught methods for testing for *dxr* specific activity in the specification on page 18, 3<sup>rd</sup> and 4<sup>th</sup> paragraphs (response page 14). Applicant merely recites that expression constructs are assayed for *dxr* specific activity has not recited any method steps, reagents, or conditions for measuring *dxr* specific activity and thus has not provided guidance for enabling the isolation of the broad category of polynucleotides encoding polypeptides having *dxr* specific activity.

Applicant asserts that the Examiner's assertion of a non-limiting role for 1-deoxy-D-xylulose 5-phosphate reductoisomerase is mistaken because the Estevez *et al.* reference suggests that the role of *dxr* is less clear and that *dxr* activity may or may not be limiting depending upon

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the species (response page 14). Applicant's arguments only confirm the uncertainty and unpredictability in using *dxr* to alter isoprenoid biosynthetic flux.

Applicant asserts that the overexpression of *dxr* in peppermint led to increases in isoprenoid synthesis (response page 14). The reference states that transgenic up regulation of *dxr* led to an increase in essential oil accumulation i.e. monoterpenes (page 8919 column 2 1<sup>st</sup> paragraph). The reference does not support the broadly claimed increases for any isoprenoid in any plant in any plant part. The cDNA used in the reference is from peppermint and not *Arabidopsis* as that taught in the specification and the transformation of peppermint with *dxr* using a constitutive promoter resulted in an increase of flux towards monoterpene biosynthesis in the oil glands of the plant. Although total *dxr* activity was greater in the leaves of transformed plants when compared to wild type plants there is no indication that all isoprenoids were enhanced in all parts of the plant by constitutive expression of the peppermint *dxr* cDNA. The results suggest that *dxr* activity is only limiting in certain tissues and during specific times during development.

Applicant has not responded to the Examiners remarks in the enablement rejection with respect to the Linthorst H. *et al.* (The Plant Cell, March 1989; Vol. 1; pp. 285-291).

Claims 21-34 and 36-39 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1 encoding a 1-deoxy-D-xylulose 5-phosphate reductoisomerase and plants transformed with said polynucleotide.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.  
October 15, 2003



**ASHWIN D. MEHTA, PH.D**  
**PATENT EXAMINER**